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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,952	03/30/2001	Charles David Claude	1225.003US1	6598

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EXAMINER
DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
1616	11

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/822,952	CLAUDE, CHARLES DAVID	
	Examiner	Art Unit	
	Robert M DeWitty	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☒ Claim(s) *44-47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-17, and 44-47 are pending in the instant application. Acknowledgement is made of Applicant's amendment and response filed 5/2/02.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-17 and 44-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment filed 5/2/02 adds material which is not supported by the original disclosure as follows: "the polymeric drug-enriched phase being substantially or completely insoluble in the bulk polymer phase" and "the drug having preferential solubility for the polymeric drug-enriched phase than the bulk polymer phase wherein the bulk polymeric phase is substantially or completely devoid of the drug". The examiner acknowledges that at page 4, line 12-21, applicant teaches a method wherein a drug enriched polymer is substantially insoluble in the bulk polymer, however there is no support for a drug release system which contains this limitation. Appropriate correction is required.

W/D

page 4 line 16-

specification recites "within"
"within" is a broad term it doesn't necessary have to be subst. or comp. insoluble. "within" could be a suspension in a suspension one substance is incorporated in another in a broad sense.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 2, 4, 5, 10, 11, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Eury et al. (U.S. Pat. No. 5,605,696).

Eury teaches a polymeric material containing a therapeutically effective amount of a drug that can be combined with a the structure of an intravascular stent (col. 3, lines 15-20). The drug can be an anticoagulant, antiplatelet, or antithrombin (col. 3, lines 60-65). The polymeric material in which the drug is incorporated can be poly(ethylene-co-vinyl acetate), poly(vinyl acetate), poly-DL-lactic acid, poly-L-actic acid, polyorthoesters, polyiminocarbonates, aliphatic polycarbonates, or polyphosphazenes (col. 4, lines 37-54).

A rate controlling membrane can also be applied over the drug loaded polymer to limit the release rate of the therapeutic drug. The rate controlling membrane can include a porosigen, such porosigen being a copolymer. As shown, at column 5, lines 8-17, the therapeutic drug and porosigen material can be contained within the polymeric material.

3. Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Hossainy et al. (U.S. Pat. No. 6,153,252).

Hossainy teaches stents having coats, such coat consisting of a biocompatible

polymer. Polyethylene glycols are suitable polymers. A top coating may further be added to delay release of an active agent that may be contained in the biocompatible polymer.

Response to Arguments

4. Applicant's arguments filed 5/2/02 have been fully considered but they are not persuasive.

Applicant asserts that Eury and Hossainy do not contain the limitations as stated above (see Response to Amendment), namely a bulk polymer phase; drug incorporated into the drug-enriched phase. However, Eury clearly teaches a polymeric material, and a drug and porsigen material that can be contained within the polymeric material. It is the understanding of the examiner that the polymeric material can be considered a bulk polymer, and the drug and posigen material can be considered a drug-enriched phase. Hossainy teaches a film-forming polymer used over a stent, with a top coating placed over the polymer. The film-forming polymer can be used to deliver therapeutic and pharmaceutical agents, and the top coating can be used to delay release a pharmaceutical agent. It is the view of the examiner that the topcoat can be considered a bulk polymer, and the film-forming polymer a drug-enriched phase.

For new claims 44-47, it is not evident where a drug release system for a stent containing a first polymer and a second polymer being significantly or completely insoluble in the first polymer is taught in the instant application. As shown by Eury et

al., the polymeric material can be poly (ethylene-co-vinyl acetate). Eury also teaches that a drug and porsigen material can be contained within the polymeric material. Thus, the rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
August 2, 2002

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616